

**Remarks**

Claims 1-101 are pending in this application. Claims 73-78, 89, 90 and 97-100 are rejected and claims 1-72, 79-88, 91-96 and 101 are withdrawn from consideration. Claims 73, 75-78, 89 and 97-98 has been cancelled without prejudice or disclaimer with this amendment. Claims 74, 90, 99 100 and 101 have been amended herein. The amendments to claims 74, 90, 99 100 and 101 are being made for reasons of clarity only and not for patentability. Thus no new matter has been added by this amendment.

With respect to all amendments and cancelled claims (and/or subject matter related thereto), Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any such subject matter in future continuation and/or divisional application.

Reconsideration of the application in view of the following is respectfully requested.

**Withdrawal of Claim 101**

By preliminary amendment dated December 6, 2002, Applicants introduced new claim 101. The Office has withdrawn this claim from consideration as directed to an invention that is independent or distinct from the invention originally claimed. Applicants respectfully traverse this withdrawal for the reasons presented below.

Upon review of the preliminary amendment as filed, Applicants have realized that the Examiner's attention was inadvertently drawn to an incorrect location within the specification for support of the subject matter of claim 101. Support for claim 101 may be found in the specification, for example at page 8, line 21-22; and in Example 5-4 at page 71, line 26 to page 72, line 6. Thus, as will be apparent from the specification, the nucleic acid sequence of claim 101 is a human sequence. Applicants apologize for this inadvertent error and respectfully request reconsideration of the withdrawal of claim 101.

**Objections to the Claims**

Claims 73-78, 89, 90 and 97 100 are objected to because of informalities. Cancellation of claims 73, 75-78, 89, 97 and 98 render the Examiner's objections with respect to those claims moot. Claims 74, 90, 99 and 100 have been amended, for reasons of clarity only and not for patentability, as suggested by the Examiner. It is noted for the record that Applicants' willingness to change "a" to "the" is considered a change of form to the claim to accommodate the USPTO's convention with respect to dependent claims but in no way is intended to indicate that any dependent claim encompasses only a single composition. Accordingly, withdrawal of this objection is respectfully requested.

**Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 73-78, 89, 90 and 97-100 are rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification. Cancellation of claims 73, 75-78, 89, 97 and 98 render the Examiner's rejections with respect to those claims moot. With respect to claims 74, 90, 99 and 100, use of the word "a" in "a human adenylylcyclase VI" has been interpreted by the Office to include allelic variants, fragments and homologs of SEQ ID NO:11. In the interest of advancing prosecution of the present application, and not for reasons of patentability, Applicants have elected to amend claim 74 (from which claims 90, 99 and 100 depend) to reflect the language suggested by the Examiner, namely, to replace "a" with "the". Accordingly, withdrawal of this ground of rejection is respectfully requested.

The Office has also suggested that the specification lacks adequate teachings for one of skill in the art to "predict the structure of DNA having an activity that is specific to AC<sub>VI</sub>, particularly human AC<sub>VI</sub>" and that thus "claiming a DNA encoding a protein only by the structure as in claims 74-77" is too broad. Applicants respectfully traverse for reasons presented herein below.

Claims 75-77 have been cancelled without prejudice or disclaimer thereby rendering the Examiner's rejection with respect to those claims moot. As presently pending, claim 74 is directed

to a nucleic acid encoding a protein of defined amino acid sequence (SEQ ID NO:11). Further, Applicants have provided an exemplary specific nucleic acid sequence (SEQ ID NO:10) encoding the human adenylylcyclase of SEQ ID NO:11. Those of skill in the art at the time the present application was filed were well aware of the degeneracy of the genetic code and thus able to predict additional nucleic acid sequences within the scope of the presently pending claim. Applicants assume this particular rejection as to claim 74 was motivated by the Office's interpretation of "a" in "a human adenylylcyclase" as encompassing variants and fragments of the protein of SEQ ID NO:11. It is respectfully submitted that Applicants amendment herein of claim 74 to recite "the" as suggested by the Examiner, overcomes this rejection. Thus, Applicants respectfully submit that all rejections under 35 U.S.C. § 112, first paragraph have been overcome and withdrawal of the same is kindly requested.

#### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 73-78, 89, 90 and 97-100 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. With respect to claims 73, 75-78, 89 and 97-98, this rejection has been rendered moot by Applicants election to cancel said claims. With respect to the claims 74, 90, 99 and 100, this rejection is respectfully traversed for the reasons presented herein below.

Claim 74 was rejected as allegedly encompassing nucleic acid sequences encoding fragments of the protein in SEQ ID NO:11. Without acquiescing that such is the case, Applicants have elected to amend claim 74 to recite "the human adenylylcyclase" as opposed to "a human adenylylcyclase" as suggested by the Examiner. Thus, it is respectfully submitted this rejection as to this claim is overcome.

Claim 99 was rejected as allegedly indefinite in its recitation of "lipid-based vector." While Applicants believe the term "lipid-based vector" would be readily understood by one of skill in the art to encompass gene delivery vectors comprising lipids, they have elected to amend this claim to more precisely point out and claim certain aspects of the present invention. Thus, whereas claim 99 is a dependent claim and its amendment is not believed to adversely affect the scope of

claims not dependent on it, and in the interest of expediting prosecution of the present application, Applicants have amended claim 99 to recite liposome vectors. It is respectfully submitted that this rejection as to this claim is overcome.

Claim 100 was rejected as allegedly indefinite in its recitation of "said vector." In particular, it was suggested that it was unclear whether "said vector" refers to the "viral vector" or the "lipid-based vector". This rejection is respectfully traversed. Claim 100, as originally filed, depends from claim 90. Claim 90 recites only "a vector"; with no reference to either viral or lipid-based vectors. Applicants respectfully submit that this rejection may have resulted from an inadvertent assumption that claim 100 depended from claim 99, rather than from claim 90.

In view of the foregoing, Applicants respectfully submit that rejection of the pending claims under 35 U.S.C. §112, second paragraph have been overcome and withdrawal of the same is kindly requested.

**Rejections under 35 U.S.C. § 102**

Claims 73-78, 89 and 90 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ishikawa (1993; GenBank AAQ4525) or Katsushika (1992, PNAS, Vol. 18, pg 8774-8778) and under 35 U.S.C. §102(e) as allegedly being anticipated by Tomlinson (US Patent 6,465,237, Oct. 15, 2002). With respect to claims 73, 75-78 and 89, these rejections have been rendered moot by cancellation of said claims. With respect to claims 74 and 90, based upon the amendments and remarks herein, these rejections are respectfully traversed.

In making this rejection, the Office alleges that claim 74 encompasses fragments of the protein of SEQ ID NO:11 (by reference to the rejection of this claim under 112/2nd). The Office alleges that Ishikawa and Katsushika teach DNA encoding a fragment of SEQ ID NO:11 and that Tomlinson teaches a nucleic acid sequence having 97% homology to SEQ ID NO:1 of the present application. Claim 74 (and therefore claim 90 as dependent thereon) has been amended to recite "the" human adenylylcyclase, as suggested by the Examiner, thus distinguishing the subject matter of this claim from a nucleic acid sequence encoding a fragment of human AC<sub>VI</sub> as is described by SEQ ID NO.1. Therefore, Applicants respectfully submit that this rejection has been obviated and kindly request withdrawal of the same.

It is noted that Applicants specifically do not acquiesce that the present application or any particular subject matter taught therein is not entitled to the full priority as claimed. Whereas Applicants have elected to amend claim 74 to distinguish the subject matter thereof from the subject matter of SEQ ID NO:1 and thus obviate this rejection, Applicants have likewise rendered moot the issue of priority for the purposes of prosecution of the presently pending claims.

**Rejections under 35 U.S.C. § 103**

Claims 73-78, 89 and 90 are 97-100 are rejected under 35 U.S.C. §103(a) as being unpatentable over by Ishikawa (1993; GenBank AAQ4525) or Katsushika (1992, PNAS, Vol. 18, pg 8774-8778) in view of Iyengar (US Patent 6,034,071). As stated elsewhere herein, claims 74-78, 89, 97 and 98 have been cancelled without prejudice or disclaimer. Thus, this rejection as to those

claims has been rendered moot. With respect to the remaining claims, this rejection is respectfully traversed. The Office refers to its rejection of claim 74 under 35 U.S.C. §102 to maintain the present rejection of that claim, stating that rejection of the remaining claims is based upon the combination of the §102 references with the Iyengar reference. Thus, having obviated the rejection of claim 74 under 35 U.S.C. §102 by amending that claim to recite “the human adenylylcyclase” rather than “a human adenylylcyclase” and thereby removing the §102 references, Applicants have likewise obviated the present rejection of all pending claims under 35 U.S.C. §103.

**CONCLUSION**

Applicants respectfully submit that all objections and rejections have been overcome and/or rendered moot and that the presently pending claims are in condition for allowance. Should the Examiner believe any issues remain unresolved, he is invited to telephone the undersigned at (650) 813-5777 to discuss such concerns and/or arrange for an interview in order to continue with an expeditious prosecution of this application.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 220002056723. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 16, 2003

Respectfully submitted,

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